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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,994	11/06/2001	Victor Raso	BBRI-2005	1367

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 09/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/992,994

Applicant(s)

RASO, VICTOR

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/25/02, 6/13/03 and 7/18/03.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-84 is/are pending in the application.
- 4a) Of the above claim(s) 60-63, 79-82 and 84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-59, 64-78 and 83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Applicant's election without traverse of Group I, claims 37-59, 64-78 and 83 in Paper No. 11 is acknowledged.

Claims 60-63, 79-82 and 84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

The disclosure is objected to because of the following informalities:

The first paragraph does not contain a reference to the parent applications as required.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64-78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific substantial asserted utility or a well established utility.

The specification teaches that a catalytic antibody that will hydrolyze and/or disaggregate preformed  $\beta$ -amyloid plaques has been made. In addition, this antibody will cross the blood brain barrier because it will bind to a transferrin receptor. This catalytic antibody was made using a transition

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state analog containing a statine analog. Nowhere is the utility of a "vaccine composition comprising a  $\beta$ -amyloid epitope" taught and/or its utility shown. A "vaccine composition" infers that the composition confers some immunological protection upon the recipient. Therefore it is maintained that such a composition has no specific substantial utility, absent a very convincing showing to the contrary.

Claims 64-78 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 37-59 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification teaches that an antibody was made using a statine analog of a transition state that would disaggregate preformed  $\beta$ -amyloid plaques and also had the ability to cross the blood-brain barrier. Nowhere is it taught that such an antibody has the ability to inhibit the formation of  $\beta$ -amyloid plaques. The process to form the plaques could well involve other processes that are not affected by the antibody. In any case, the specification does not teach that this antibody will do this. Therefore, applicant have not taught one of ordinary skill in the art to make the antibody of the instant claims.

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Claims 64-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification teaches the production of an antibody that will cleave and/or disaggregate a preformed  $\beta$ -amyloid plaque. This antibody was made using a statine analog of a transition state. Nowhere in the specification is it taught that a catalytic antibody can be made using other than a statine analog and nowhere is it taught that a "vaccine composition comprising a  $\beta$ -amyloid epitope" that does not meet the other requirements outlined *supra* will cleave  $\beta$ -amyloid or have any other activity. The specification also does not teach how such a "vaccine composition comprising a  $\beta$ -amyloid epitope" can be used. Therefore applicants have not taught how to make and/or use the instant claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 64 and 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki, et al. (A). The instant reference teaches in column 15, lines 42-53 a composition of  $\beta$ -amyloid antigens together with Freund's adjuvant. Since the elements of the instant claims are present the description of the composition as a vaccine is immaterial to the patentability of the composition.

Claims 64-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Suzuki, et al. (A) or Anderson (B). Suzuki, et al. is characterized *supra*. Since the reference recites " $\beta$ -amyloid antigens" it is maintained this reads on all epitopes from all regions of the protein. It is also maintained that claim 77-78 are taught by the reference, at least inherently.


Anderson in column 11, lines 26-46 teaches the use of "a  $\beta$ -amyloid peptide preparation" along with Freund's adjuvant. It is maintained that "a  $\beta$ -amyloid peptide preparation" reads on all epitopes from all regions of the protein. It is also maintained that claim 77-78 are taught by the reference, at least inherently.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
September 5, 2003